# Complete Summary

## GUIDELINE TITLE

Revised guidelines for HIV counseling, testing, and referral.

## BIBLIOGRAPHIC SOURCE(S)

Revised guidelines for HIV counseling, testing, and referral. MMWR Recomm Rep 2001 Nov 9;50(RR-19):1-58. [151 references] PubMed

## COMPLETE SUMMARY CONTENT



## SCOPE

### DISEASE/CONDITION(S)

Human immunodeficiency virus (HIV) infection

### GUIDELINE CATEGORY

Counseling
Prevention
Screening

### CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Preventive Medicine
Psychology

### INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel

Nurses
Physician Assistants
Physicians
Public Health Departments
Social Workers

### GUIDELINE OBJECTIVE(S)

- To revise and update several sets of Centers for Disease Control and Prevention (CDC) guidelines for HIV counseling, testing, and referral (CTR).
- To ensure that HIV-infected persons and persons at increased risk for HIV:
    - Have access to HIV testing to promote early knowledge of their HIV status;
    - Receive high-quality HIV prevention counseling to reduce their risk for transmitting or acquiring HIV; and
    - Have access to appropriate medical, preventive, and psychosocial support services.
- To promote early knowledge of HIV status through HIV testing and ensure that all persons either recommended for or currently receiving HIV testing are provided information regarding transmission, prevention, and the meaning of HIV test results.

### TARGET POPULATION

- HIV-infected persons
- Persons at increased risk for HIV infection

### INTERVENTIONS AND PRACTICES CONSIDERED

Provision of the following routine or targeted services in traditional and nontraditional health care settings:

1. HIV counseling
2. HIV testing
3. HIV referral

### MAJOR OUTCOMES CONSIDERED

- Knowledge of high-risk behaviors for HIV transmission
- Modification of high-risk behaviors based on counseling
- Acquisition of human immunodeficiency virus
- Transmission of human immunodeficiency virus

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

## DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A survey was conducted of publicly funded sites that offer HIV counseling, testing, and referral to assess user satisfaction with the 1994 Centers for Disease Control and Prevention (CDC) guidelines for HIV counseling testing, and referral (HIV counseling, testing, and referral standards and guidelines. Atlanta [GA]: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, 1994). Internal and external content specialists were consulted on key areas to address. Approximately 5,000 abstracts were screened and approximately 600 relevant publications were reviewed and synthesized where appropriate. Approximately 20 previously published Centers for Disease Control and Prevention guidelines related to HIV counseling, testing, and referral also were summarized.

## NUMBER OF SOURCE DOCUMENTS

Not stated

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

## METHODS USED TO ANALYZE THE EVIDENCE

Review

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A panel of technical specialists from public and private sectors; government and nongovernment agencies; and legal, ethics and policy fields was convened to review the recommendations. Internal Centers for Disease Control and Prevention (CDC) comments, public and private provider assessments, key consultant interviews, broad external reviews, and public comments through the Federal Register were obtained.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

#### HIV Counseling, Testing, and Referral -- Goals and General Principles

Goals of HIV Counseling, Testing, and Referral

- Ensure that HIV-infected persons and persons at increased risk for HIV:
  - have access to HIV testing to promote early knowledge of their HIV status;
  - receive high-quality* HIV prevention counseling to reduce their risk for transmitting or acquiring HIV; and
  - have access to appropriate medical, preventive, and psychosocial support services.
- Promote early knowledge of HIV status through HIV testing and ensure that all persons either recommended or receiving HIV testing are provided information regarding transmission, prevention, and the meaning of HIV test results.

*Delivered according to recommended protocols (for counseling, referral, and evaluation) or regulatory standards (for testing).

Principles of HIV Counseling, Referral, and Testing

Effective HIV counseling, referral and testing is based on the following principles:

- Protect confidentiality of clients who are recommended or receive HIV counseling, referral, and testing services. Information regarding a client's use of HIV counseling, referral, and testing services should remain private (i.e., confidential). Personal information should not be divulged to others in ways inconsistent with the client's original consent.
- Obtain informed consent before HIV testing. HIV testing should be voluntary and free of coercion. Informed consent before HIV testing is essential. Information regarding consent may be presented orally or in writing and should use language the client can understand. Accepting or refusing testing must not have detrimental consequences to the quality of care offered. Documentation of informed consent should be in writing, preferably

with the client's signature. State or local laws and regulations governing HIV testing should be followed.

Information regarding consent may be presented separately from or combined with other consent procedures for health services (e.g., as part of a package of tests or care for certain conditions). However, if consent for HIV testing is combined with consent for other tests or procedures, the inclusion of HIV testing should be specifically discussed with the client. For a discussion of HIV testing in pregnant women, consult the guidelines for HIV screening of pregnant women (see the related guidelines titled "Revised Recommendations for HIV Screening of Pregnant Women" [MMWR Recomm Rep 2001 Nov 9;50(RR-19):59-86; a related National Guideline Clearinghouse (NGC) Guideline Summary is also available]).

- Provide clients the option of anonymous HIV testing. Anonymous testing (i.e., consented voluntary testing conducted without a client's identifying information being linked to testing or medical records, including the request for testing or test results) has been used widely and effectively. Anonymous testing can benefit the health of individual persons and the public by prompting earlier entry into medical care. Persons who would otherwise not be tested might seek anonymous HIV testing and learn their HIV status. Consistent with public health best practices, states in which anonymous testing is not available should reconsider their policy. When the client has no clear preference regarding testing type, confidential testing (i.e., information documented in client's record) should be recommended to promote receipt of test results and linkage to follow-up counseling and referral for needed services. Clients opting for anonymous testing should be informed that the provider cannot link the client's test result to the client by name. Therefore, if the client does not return for test results, the provider will not be able to contact the client with those results.
- Provide information regarding the HIV test to all who are recommended the test and to all who receive the test, regardless of whether prevention counseling is provided. The information should include a description of ways in which HIV is transmitted, the importance of obtaining test results, and the meaning of HIV test results.
- Adhere to local, state, and federal regulations and policies that govern provision of HIV services. Laws at the local, state, and federal levels might address aspects of HIV services or regulate how services are provided to particular persons (e.g., minors). In addition, policies, local ordinances, funding source requirements, and planning processes could also affect a provider's decisions regarding which services to provide and how to provide them.
- Provide services that are responsive to client and community needs and priorities. Providers should work to remove barriers to accessing services and tailor services to individual and community needs. To ensure that clients find services accessible and acceptable, services can be offered in nontraditional settings (i.e., community-based or outreach settings); hours of operation can be expanded or altered; unnecessary delays can be eliminated (e.g., integrating counseling and testing for sexually transmitted diseases (STDs)/HIV with counseling and testing for hepatitis); test results can be obtained more easily (e.g., with rapid testing or by telephone in certain

situations); and less-invasive specimen collection can be used (e.g., oral fluid, urine, or finger-stick blood).

- Provide services that are appropriate to the client's culture, language, sex, sexual orientation, age, and developmental level. These factors could affect how the client seeks, accepts, and understands HIV services. Providers should consider these factors when designing and providing HIV services to increase the likelihood of return for test results and acceptance of counseling and referral services.
- Ensure high-quality services. To ensure ongoing, high-quality services that serve client and community needs, providers should develop and implement written protocols for counseling, referral, and testing and written quality assurance and evaluation procedures. Many state and local health departments have substantial expertise in providing and monitoring the quality of HIV counseling, referral, and testing services and can be a resource to private providers or community-based or outreach settings initiating these services.

## Targeted Versus Routinely Recommended HIV Counseling, Referral, and Testing

Providers in all settings (traditional and nontraditional) should ideally recommend counseling, referral, and testing to all clients on a routine basis to ensure that all clients who could benefit from counseling, referral, and testing receive these services. However, resources might be insufficient to permit this practice. Therefore, these guidelines contain recommendations aimed at ensuring that as many persons as possible who are HIV-infected or at risk for HIV who do not know their HIV status have access to testing, prevention counseling, and referrals.

### Routinely Recommending Counseling, Referral, and Testing to All Clients Versus Targeting Counseling, Referral, and Testing to Selected Clients

Studies have documented that, in settings serving clients at increased behavioral and clinical risk for HIV infection, targeting HIV testing based on reported risk factors will miss many HIV-infected clients. However, in low prevalence settings, where most clients have minimal risk, targeting clients for HIV testing based on risk screening might be more feasible for identifying small numbers of HIV-infected persons. Providers should consider three factors in determining whether to recommend HIV counseling, referral, and testing to all clients or to target only selected clients.

- Type of setting
- HIV prevalence of the setting
- Behavioral and clinical HIV risk of the individual clients in the setting

Although certain types of settings serve populations at increased risk (e.g., sexually transmitted disease clinics), others might serve individual clients at increased risk (e.g., private physicians' offices in areas of low prevalence). Individual risk can be ascertained through risk screening. Under certain circumstances -- perinatal transmission, acute occupational exposure, and acute nonoccupational (i.e., high-risk sexual or needle-sharing) exposure -- providers should recommend HIV counseling, referral, and testing regardless of setting prevalence or behavioral or clinical risk, based on the respective guidelines (see

the related guidelines titled "Revised Recommendations for HIV Screening of Pregnant Women" [MMWR Recomm Rep 2001 Nov 9;50(RR-19):59-86; a related National Guideline Clearinghouse (NGC) Guideline Summary is also available]).

## Using Prevalence Data to Establish Service Priorities

Few data exist to define "high" and "low" HIV prevalence and describe how these definitions could help develop and prioritize HIV counseling, referral, and testing services. A study conducted in the early 1990s for acute care hospitals with ≥1% HIV prevalence reported that routine voluntary HIV testing of all patients within a specific age range could be a feasible way to identify a large proportion of HIV-infected patients. This 1% prevalence can be used as general guidance for whether to routinely recommend or target HIV counseling and testing in other settings.

The threshold of HIV prevalence that should lead to routine recommendations for HIV testing of all clients within a setting can vary within and across settings and should be set in consideration of available resources. Services could be routinely recommended in settings with HIV prevalence rates

Because of the availability of antiretroviral therapy to reduce the risk for perinatal HIV transmission, all pregnant women should be recommended HIV testing regardless of setting prevalence or behavioral or clinical risk (see the related guidelines titled "Revised Recommendations for HIV Screening of Pregnant Women" [National Guideline Clearinghouse (NGC) Guideline Summary is also available]).

## Determining Individual HIV Risk Through Risk Screening*

A client's individual HIV risk can be determined through risk screening based on self-reported behavioral risk (see Box 2 titled "Examples of Two Risk-Screening Strategies to Elicit Client-Reported HIV Risks" in the original guideline document) and clinical signs or symptoms. Behavioral risks include injection-drug use or unprotected intercourse with a person at increased risk for HIV. Clinical signs and symptoms include sexually transmitted diseases, which indicate increased risk for HIV infection, or other signs or symptoms (e.g., of acute retroviral or opportunistic infections), which might suggest the presence of HIV infection. Insufficient data exist to support the efficacy of any one risk-screening approach over others (e.g., face-to-face discussion or interviews, self-administered questionnaires, computer-assisted interviews, or simple open-ended questions asked by providers).

[*]Risk screening differs from risk assessment, which is part of HIV prevention counseling (see the section titled "HIV Prevention Counseling").

### Recommendations for Routinely Recommended and Targeted Counseling, Testing, and Referral by Setting and Circumstance

Decisions regarding whether to recommend routine or targeted services are based on the behavioral and clinical HIV risk of the client population in the setting, the level of HIV prevalence of the setting, and the behavioral and clinical HIV risk of individual clients. These factors should not be used to determine recommendations for counseling, testing, and referral in circumstances in which treatment potential exists (i.e., perinatal transmission and acute occupational or non-occupational exposure).

Clients who should be recommended HIV prevention counseling, testing, and referral include the following:

- All clients in settings serving client populations at increased behavioral or clinical HIV risk (regardless of setting HIV prevalence).
- Individual clients in settings with <1%[*] HIV who[**]
    - have clinical signs or symptoms suggesting HIV infection (e.g., fever or illness of unknown origin, opportunistic infection [including active tuberculosis disease] without known reason for immune suppression),
    - have diagnoses suggesting increased risk for HIV infection (e.g., another sexually transmitted disease [STD] or blood-borne infection),
    - self-report HIV risks (see Box 2 titled "Examples of Two Risk-Screening Strategies to Elicit Client-Reported HIV Risks" in the original guideline document) or,
    - specifically request an HIV test
- All clients in setting with a ≥1%[***] HIV prevalence.[****]
- Regardless of setting prevalence or behavioral risk:
    - all pregnant women,[****]
    - all clients with possible acute occupational exposure, and
    - all clients with known sexual or needle-sharing exposure to an HIV-infected person.

[*] Or lower than other settings in the community.

[**] Constitutes risk screening; see the section titled "Determining Individual HIV Risk Through Risk Screening."

[***] Or higher than other settings in the community.

[****] Clients should be routinely recommended testing, and if risk is identified during risk screening, they should also be recommended HIV prevention counseling and referral.

### Settings Serving Populations at Increased Behavioral or Clinical Risk

HIV counseling, testing, and referral should be routinely recommended for all clients in settings where the client population is at increased behavioral or clinical

risk for acquiring or transmitting HIV infection, regardless of setting prevalence. These services should be provided on-site. In these settings, clients with ongoing risk behaviors should be linked to additional HIV prevention and support services (e.g., partner counseling and referral services [PCRS], drug or alcohol prevention and treatment), as appropriate. HIV-infected clients should receive ongoing HIV prevention counseling applicable to their personal situation.

Examples of settings that serve populations at increased behavioral or clinical risk for HIV infection include:

- Adolescent or school-based health clinics with high rates of sexually transmitted diseases
- Clinics serving men who have sex with men
- Correctional facilities, prisons, juvenile detention centers
- Drug or alcohol prevention and treatment programs
- Freestanding HIV test sites
- Homeless shelters
- Outreach programs (e.g., syringe exchange programs)
- Sexually transmitted disease clinics
- Tuberculosis (TB) clinics (Note: Only persons with confirmed or suspected tuberculosis and their contacts should routinely be recommended for HIV counseling, testing, and referral.)

### Low Prevalence Settings

In low prevalence settings (e.g., <1%; see the section titled "Using Prevalence Data to Establish Service Priorities") where the client population is generally not at increased behavioral or clinical HIV risk, counseling, testing, and referral should be targeted to clients based on risk screening. Prevention counseling and referral are recommended for persons at increased risk even if HIV testing is declined. Any client who requests HIV testing should receive it, regardless of risk. These settings likely represent most health-care settings.

### High Prevalence Settings

In high prevalence settings (e.g., $\geq$1%), all clients should be routinely recommended HIV testing. Risk screening should be used to determine if HIV prevention counseling and referral should also be recommended. Counseling, testing, and referral should be provided on-site. In these settings, clients with ongoing risk behaviors identified during risk screening should be linked to additional HIV prevention and support services (e.g., partner counseling and referral services and drug or alcohol prevention and treatment), as appropriate.

### Circumstances For Which HIV Preventive Treatment Exists

Prophylaxis exists for a limited number of situations: perinatal transmission, acute occupational exposure, and acute non-occupational (i.e., high-risk sexual or needle-sharing) exposure. Regardless of population risk, setting prevalence, or individual behavioral or clinical risk, voluntary HIV testing should be routinely recommended to (a) all pregnant women, (b) clients with acute occupational exposure, and (c) clients with acute non-occupational (e.g., high-risk sexual or needle-sharing) exposure. Regardless of whether a client receives an HIV test,

HIV prevention counseling and referral should target pregnant women based on risk screening and be routinely recommended to clients with either acute occupational or non-occupational exposures. For further information, consult the respective guidelines on perinatal transmission, acute occupational exposure, and acute non-occupational exposure (see the related guidelines titled "Revised Recommendations for HIV Screening of Pregnant Women" [MMWR Recomm Rep 2001 Nov 9;50(RR-19):59-86; a related National Guideline Clearinghouse (NGC) Guideline Summary is also available]).

## A Framework for Implementing HIV Counseling, Testing, and Referral

Counseling, testing, and referral are interrelated interventions that ideally should be integrated and offered in all settings. However, these guidelines acknowledge public and private providers' needs for flexibility. Certain providers might be able to offer prevention counseling but not an HIV test, whereas others might be able to offer an HIV test but not prevention counseling. Although all providers in settings serving populations at increased behavioral or clinical risk for HIV (e.g., sexually transmitted disease clinics) should provide HIV counseling, testing, and referral on-site, not all can. These providers should maintain clear and appropriate methods of referral to providers of prevention counseling or testing elsewhere. To ensure client referral, providers who offer HIV counseling and testing should collaborate with providers serving populations at increased risk for HIV who might not provide these services.

### HIV Counseling

HIV counseling seeks to reduce HIV acquisition and transmission through the following:

- Information. Clients should receive information regarding HIV transmission and prevention and the meaning of HIV test results. Provision of information is different from informed consent.
- HIV prevention counseling. Clients should receive help to identify the specific behaviors putting them at risk for acquiring or transmitting HIV and commit to steps to reduce this risk. Prevention counseling can involve ≥1 sessions.

### Information

All clients who are recommended or who request HIV testing should receive the following information, even if the test is declined:

- Information regarding the HIV test and its benefits and consequences
- Risks for transmission and how HIV can be prevented
- The importance of obtaining test results and explicit procedures for doing so
- The meaning of the test results in explicit, understandable language
- Where to obtain further information or, if applicable, HIV prevention counseling
- Where to obtain other services (see the section titled "Typical Referral Needs").

In certain settings where HIV testing is offered, other useful information includes (a) descriptions or demonstrations of how to use condoms correctly; (b) information regarding risk-free and safer sex options; (c) information regarding other sexually transmitted and blood-borne diseases; (d) descriptions regarding the effectiveness of using clean needles, syringes, cotton, water, and other drug paraphernalia; (e) information regarding drug treatment; and (f) information regarding the possible effect of HIV vaccines on test results for persons participating in HIV vaccine trials (see the section titled "Additional Counseling Considerations for Special Situations and Positive HIV Test Results").

For efficiency, information can be provided in a pamphlet, brochure, or video rather than a face-to-face encounter with a counselor. This approach allows the provider to focus face-to-face interactions on prevention counseling approaches proven effective with persons at increased risk for HIV infection. Information should be provided in a manner appropriate to the client's culture, language, sex, sexual orientation, age, and developmental level. Certain informational videos and large-group presentations that provide explicit information regarding correct use of condoms have proven effective in reducing new sexually transmitter diseases and could be effective in reducing HIV.

### HIV Prevention Counseling

HIV prevention counseling should focus on the client's own unique circumstances and risk and should help the client set and reach an explicit behavior-change goal to reduce the chance of acquiring or transmitting HIV. HIV prevention counseling is usually, but not always, conducted in the context of HIV testing. The client-centered HIV prevention counseling model involves two brief sessions, whereas other effective models are longer or involve more sessions. Regardless of the model used, in HIV prevention counseling, the counselor or provider focuses on assessing the client's personal risk or circumstances and helping the client set and reach a specific, realistic, risk-reduction goal. These guidelines avoid using the terms "pretest" and "posttest" counseling to underscore that prevention counseling is a risk-reduction process that might involve only one or >1 session.

Several models for HIV prevention counseling in conjunction with HIV testing have been developed, evaluated in controlled studies, and documented to be efficacious in changing behavior or reducing sexually transmitted infections, including individual face-to-face counseling, large- and small-group counseling with a facilitator, and video-based counseling. For more information regarding interventions, see the document titled "The Compendium of HIV Prevention Interventions with Evidence of Effectiveness" at the Centers for Disease Control and Prevention Web site.

### Client-Centered HIV Prevention Counseling

Since 1993, the Centers for Disease Control and Prevention has recommended one interactive counseling model, called client-centered HIV prevention counseling, which involves two face-to-face sessions with a provider or counselor. This model has traditionally used a two-step HIV testing approach in which clients are physically present at a setting for the HIV test (initial session) and then return for HIV test results (follow-up session). Each session might require 15 to 20 minutes (including testing and referral) for clients at increased risk for HIV, but

could take only a few minutes for those at lower risk. In the first session, a personalized risk assessment* encourages clients to identify, understand, and acknowledge the behaviors and circumstances that put them at increased risk for acquiring HIV. The session explores previous attempts to reduce risk and identifies successes and challenges in these efforts. This in-depth exploration of risk allows the counselor to help the client consider ways to reduce personal risk and commit to a single, explicit step to do so. In the second session, when HIV test results are provided, the counselor discusses the test results, asks the client to describe the risk-reduction step attempted (and acknowledges positive steps made), helps the client identify and commit to additional behavioral steps, and provides appropriate referrals (e.g., to partner counseling and referral services [PCRS]).

In one large, randomized, controlled trial, this model was reported to be:

- effective at reducing high-risk sexual behaviors and new sexually transmitted diseases
- feasible to use even in busy publicly funded clinics
- acceptable to clients, counselors, and health-care providers
- cost-effective at preventing sexually transmitted diseases in persons at increased risk for HIV.

The model was reported to be especially effective among adolescents and persons with ongoing sexual risk behaviors (e.g., newly diagnosed sexually transmitted diseases). Although the benefits of client-centered HIV prevention counseling in reducing high-risk drug behaviors are unknown, studies have indicated that similar counseling approaches that help clients explore risks and set specific risk-reduction goals reduce risky drug use behaviors.

Observational studies and reviews of programs in various settings have indicated that many counselors are still unfamiliar with the specific goals of the client-centered HIV prevention counseling model. Because "client-centered" is sometimes misinterpreted as "face-to-face," providers in many HIV test sites deliver face-to-face informational messages in response to a generic checklist risk assessment. This type of counseling provides advice rather than encouraging client participation or discussion of personal risk; it seldom focuses on personal goal setting. "Client-centered" can also be misinterpreted to mean that the counselor should avoid directing the session. Although attentive listening and respect for clients' concerns are important elements of effective counseling, the primary goal of client-centered HIV prevention counseling is risk reduction. HIV prevention counseling usually requires provider training and support and ongoing quality assurance to achieve optimal benefit. Providers can contact their state health department's HIV/AIDS program office for information on local training opportunities. For information on client-centered counseling with rapid testing, see the section titled "Addressing Barriers to HIV Prevention Counseling."

* Personal risk assessment is an essential element of HIV prevention counseling in which the client and counselor work to understand and acknowledge the client's personal risk for HIV. Risk assessment is not synonymous with risk screening (see the section titled "Determining Individual Client Risk Through Risk Screening," and Box 2 titled "Examples of Two Risk-Screening Strategies to Elicit Client-Reported

HIV Risks" in the original guideline document), which helps determine which clients should be recommended HIV counseling, testing, and referral.

### Elements of HIV Prevention Counseling

Regardless of the HIV prevention counseling model used, some counseling elements have been used repeatedly in effective interventions and are recognized by many specialists as critical in counseling success (Technical Expert Panel Review of Centers for Disease Control and Prevention HIV Counseling, Testing, and Referral Guidelines; February 18 to 19, 1999; Atlanta, Georgia).

The following elements should be part of all HIV prevention counseling sessions:

- Keep the session focused on HIV risk reduction. Each counseling session should be tailored to address the personal HIV risk of the client rather than providing a predetermined set of information. Although counselors must be willing to address problems that pose barriers to HIV risk reduction (e.g., alcohol use in certain situations), counselors should not allow the session to be distracted by the client's additional problems unrelated to HIV. Certain counseling techniques (e.g., open-ended questions (see Box 5 titled "Examples of Closed-Ended Versus Open-Ended Questions" in the original guideline document), role-play scenarios, attentive listening, and a nonjudgmental and supportive approach) can encourage the client to remain focused on personal HIV risk reduction.
- Include an in-depth, personalized risk assessment. Sometimes called "enhancing self-perception of risk," risk assessment allows the counselor and client to identify, acknowledge, and understand the details and context of the client's HIV risk. Keeping the assessment personal, instead of global, will help the client identify concrete, acceptable protective measures to reduce personal HIV risk (see Box 6 titled "Examples of Global Versus Specific Risk-Reduction Steps for HIV Prevention Counseling" in the original guideline document). The risk assessment should explore previous risk-reduction efforts and identify successes and challenges in those efforts. Factors associated with continued risk behavior that might be important to explore include using drugs or alcohol before sexual activity, underestimating personal risk, perceiving that precautionary changes are not an accepted peer norm, perceiving limited self-efficacy for successful change efforts, receiving reinforcement for frequent unsafe practices (e.g., a negative HIV test result after risk behaviors), and perceiving that vulnerability is associated with "luck" or "fate".
- Acknowledge and provide support for positive steps already made. Exploring previous risk-reduction efforts is essential for understanding the strengths and challenges faced by the client in reducing risk. Support for positive steps already taken increases the clients' beliefs that they can successfully take further HIV risk reduction steps. For some clients, simply agreeing to an HIV test is an important step in reducing risk.
- Clarify critical rather than general misconceptions. In most situations, counselors should focus on reducing the client's current risk and avoid discussions regarding HIV transmission modes and the meaning of HIV test results. However, when clients believe they have minimal HIV risk but describe more substantial risk, the counselor should discuss the HIV transmission risk associated with specific behaviors or activities the clients

describe and then discuss lower-risk alternatives. For example, if clients indicate that they believe oral sex with a risky sex partner poses little or no HIV risk, the counselor can clarify that, although oral sex with an infected partner might result in lower HIV transmission risk than anal sex, oral sex is not a risk-free behavior, particularly when commonly practiced. If clients indicate that they do not need to be concerned about HIV transmission among needle-sharing partners if they use clean needles, the counselor can clarify that HIV can be transmitted through the cooker, cotton, or water used by several persons sharing drugs. With newly identified or uninformed HIV-infected clients, the counselor should discuss HIV transmission risks associated with specific sexual or drug-use activities, including those in which the client might not be currently engaged.

- Negotiate a concrete, achievable behavior-change step that will reduce HIV risk. Although the optimal goal might be to eliminate HIV risk behaviors, small behavior changes can reduce the probability of acquiring or transmitting HIV. Behavioral risk-reduction steps should be acceptable to the client and appropriate to the client's situation. For clients with several high-risk behaviors, the counselor should help clients focus on reducing the most critical risk they are willing to commit to changing. The step does not need to be a personal behavior change. For many clients, knowledge of a partner's recent HIV status (and talking with the partner about getting an HIV test) might be more critical than personal behavior changes. The step should be relevant to reducing the client's own HIV risk and should be a small, explicit, and achievable goal, not a global goal (see Box 6 titled "Examples of Global Versus Specific Risk-Reduction Steps for HIV Prevention Counseling" in the original guideline document). Identifying the barriers and supports to achieving a step, through interactive discussion, role-play modeling, recognizing positive social supports, or other methods will enhance the likelihood of success. Writing down the goal might be useful. For clients with ongoing risk behaviors, referral to additional prevention and support services is encouraged
- Seek flexibility in the prevention approach and counseling process. Counselors should avoid a "one-size-fits-all" prevention message (e.g., "always use condoms"). Behaviors that are safe for one person might be risky for another. For example, unprotected vaginal intercourse might be unsafe with anonymous partners whose HIV status is unknown, but safe for uninfected persons in a mutually monogamous relationship. The length of counseling sessions will vary depending on client risk and comfort (e.g., adolescents might require more time than adults).
- Provide skill-building opportunities. Depending on client needs, the counselor can demonstrate or ask the client to demonstrate problem-solving strategies such as (a) communicating safer sex commitments to new or continuing sex partners; (b) using male latex condoms properly; (c) trying alternative preventive methods (e.g., female condoms); (d) cleaning drug-injection equipment if clean syringes are unavailable; or (e) communicating safer drug-injection commitments to persons with whom the client shares drug paraphernalia.
- Use explicit language when providing test results. Test results should be provided at the beginning of the follow-up session. Counselors should never ask the client to guess the test results. Technical information regarding the test can be provided through a brochure or other means so the session can focus on personal HIV risk reduction for clients with negative tests and other considerations for clients with positive or indeterminate test results (see the

section titled "Additional Counseling Considerations for Special Situations"). In-depth, technical discussions of the "window period (i.e., the time from when a person is infected until they develop detectable HIV antibody) should be avoided because they could confuse the client and diffuse the importance of the HIV prevention message. Counselors should clarify that negative test results do not mean the client has no HIV risk and work with the client to reconsider ongoing HIV risk behaviors and the benefits of taking steps to reduce those risks. A client with ongoing risk behaviors should not be given a false sense of the safety of those behaviors (i.e., avoid statements like "whatever you were doing seems to be safe" or "continue to do whatever you are doing now").

These counseling elements are considered necessary for high-quality counseling. Specialists in the field (Technical Expert Panel Review of The Centers for Disease Control and Prevention HIV Counseling, Testing, and Referral Guidelines; February 18 to 19, 1999; Atlanta, Georgia) also suggested adoption of the following:

- Ensure that the client returns to the same counselor. Consistency of the client and counselor relationship helps the client feel secure, reduces misunderstanding, and promotes the likelihood of effective risk reduction. Effective counseling models tended to use the same counselor for all sessions. When follow-up prevention counseling sessions must be provided by a different counselor, careful record keeping is recommended to ensure high-quality counseling. See document titled "The Compendium of HIV Prevention Interventions with Evidence of Effectiveness" at the Centers for Disease Control and Prevention Web site.
- Use a written protocol to help counselors conduct effective sessions. A structured protocol outlining session goals can help keep the counselor focused on risk reduction. The protocol can include examples of open-ended questions (to help a new counselor avoid closed-ended questions) and a list of explicit risk-reduction steps).
- Ensure ongoing support by supervisors and administrators. Supervisory support is essential for effective counseling. Training in HIV counseling approaches that focus on personal risk reduction is recommended for persons supervising counselors. Staff appraisals should acknowledge that completion of critical counseling elements has higher priority than completion of paperwork.
- Avoid using counseling sessions for data collection. If required, paperwork should be completed at the end of the counseling session or by staff members who are not counseling. Checklist risk assessments driven by data collection forms are detrimental to effective counseling because they can encourage even skilled counselors to use closed-ended questions, limit eye contact, and miss critical verbal and nonverbal cues. The relevance of any routinely collected data should be periodically assessed.
- Avoid providing unnecessary information. An emphasis on providing information might prompt counselors to miss critical HIV prevention opportunities and cause clients to lose interest. Discussion of theoretical HIV risks (e.g., sex with a person with hemophilia or needle exposures through tattoos) tends to shift the focus away from the client's actual HIV risk situations to topics that are more "comfortable" or easy to discuss but irrelevant to the client's risk.

## Who Should Deliver Prevention Counseling?

In any setting where HIV testing is provided, existing personnel can be effective counselors if they have the desire and appropriate training and employ the essential counseling elements. Advanced degrees or extensive experience are not necessary for effective HIV prevention counseling, though training is. Training in counseling is available (see the section titled "Ensuring High-Quality HIV Prevention Counseling"). In situations where primary health-care providers (e.g., physicians) might not be able to provide prevention counseling, auxiliary health professionals trained in HIV prevention counseling models can provide this service. Although peer counseling has been successful in certain situations, research does not support an explicit risk-reduction need or benefit to matching clients with counselors based on same or similar backgrounds, sex, ethnicity, age, or peer group for intervention efficacy. The following skills and counselor characteristics were identified by specialists in the field as important for effective HIV prevention counseling (Technical Expert Panel Review of Centers for Disease Control and Prevention, HIV Counseling, Testing, and Referral Guidelines; February 18 to 19, 1999; Atlanta, Georgia):

- Completion of standard training courses in client-centered HIV prevention counseling or other risk-reduction counseling models
- Belief that counseling can make a difference
- Genuine interest in the counseling process
- Active listening skills
- Ability to use open-ended rather than closed-ended questions (see Box 5 titled "Examples of Closed-Ended Versus Open-Ended Questions" in the original guideline document)
- Ability and comfort with an interactive negotiating style rather than a persuasive approach
- Ability to engender a supportive atmosphere and build trust with the client
- Interest in learning new counseling and skills-building techniques
- Being informed regarding specific HIV transmission risks
- Comfort in discussing specific HIV risk behaviors (i.e., explicit sex or drug behaviors)
- Ability to remain focused on risk-reduction goals
- Support for routine, periodic, quality assurance measures

## Additional Counseling Considerations for Special Situations

- Persons with newly identified HIV infection. Clients with newly identified HIV infection have immediate and long-term needs. Some clients might be better prepared to receive positive test results than others. The emotional impact of hearing an HIV-positive test result might prevent clients from clearly understanding information during the session in which they receive their results. Providers should provide appropriate referrals (see the section titled "Typical Referral Needs") and, when necessary, additional sessions.

  When a client receives the test result, the provider should ensure that the client understands it. As part of HIV prevention counseling, providers should explicitly discuss and clarify any misconceptions regarding HIV transmission risk to partners associated with specific sexual or needle-sharing activities. Clients should be advised to refrain from donating blood, plasma, or organs.

For sexually active clients who are not in mutually monogamous partnerships, providers should also address strategies to prevent other sexually transmitted or blood-borne infections (e.g., gonorrhea, syphilis, chlamydia, herpes simplex virus, human herpes virus type 8 [the virus linked to Kaposi sarcoma], hepatitis B virus, hepatitis C virus, and cytomegalovirus).

The first few months after persons learn they are HIV infected are important for accessing medical and other support services to help them obtain treatment and establish and maintain behavior changes that reduce the likelihood of transmitting the virus to others. For example, persons with ongoing risks might be referred for prevention counseling to prevent transmission to others or for prevention case management. For all newly identified clients, a follow-up appointment 3 to 6 months after diagnosis is recommended by some specialists to assess whether clients were able to initiate medical care, minimize transmission risk to uninfected partners, and access other needed services (e.g., partner counseling and referral services). See guidance on partner counseling and referral services and prevention case management.

- Persons with a single, recent nonoccupational HIV exposure. After a reported sexual, injection-drug use, or other nonoccupational exposure to HIV, providers should refer clients for prompt initiation of evaluation, counseling, and follow-up services. Early postexposure prophylaxis could reduce the likelihood of becoming infected with HIV, although the degree to which early treatment can prevent new infection after acute nonoccupational HIV exposure is unclear. Further guidance on nonoccupational HIV exposure is available.
- Persons with indeterminate HIV test results. Until follow-up test results are available, persons with an indeterminate result should receive information regarding the meaning of test results. HIV prevention counseling should be the same as for a person with newly identified HIV infection. Behaviors that minimize the risk for HIV transmission to sex and needle-sharing partners should be emphasized, even if the client reports no risk behaviors. Clients with repeated indeterminate test results $\geq$1 month apart are unlikely to be HIV-infected and can be provided test results in the same way as clients with negative test results, unless recent HIV exposure is suspected (see the section titled "Indeterminate Test Results").
- Persons seeking repeat HIV testing. In addition to brief prevention counseling sessions, ongoing HIV prevention counseling aimed at personal risk reduction might be useful for persons seeking repeated HIV testing who have continued HIV risk. Counselors should encourage clients to explore alternative prevention strategies and to identify and commit to additional risk-reduction steps. Clients with ongoing risk behaviors might benefit from referral to other HIV prevention and support services because their current risk behavior might be reinforced by repeated negative HIV test results or they might view HIV testing as protective. More information on prevention case management is available (see the section titled "Ongoing Exposure").
- Persons who use drugs. Persons who inject drugs might also be at increased risk for acquiring HIV through unprotected sex with an HIV-infected partner. For injection-drug users (IDUs), intervention studies indicate that personalized, interactive prevention counseling models using goal-setting strategies might be effective in reducing injection-drug and sexual-risk

behaviors. Evidence also supports the efficacy of community strategies (e.g., methadone maintenance programs or other drug treatment programs, outreach programs, and syringe exchange) to reduce new HIV infections among injection-drug users. Specialists in the field advocate recommending such strategies, along with individual HIV prevention counseling, to persons who inject drugs.

- Sex or needle-sharing partners of HIV-infected persons. Sex or needle-sharing partners of HIV-infected persons should be encouraged to have HIV prevention counseling and testing. Partners who are HIV discordant (i.e., one person is HIV infected and the other is uninfected) should receive counseling aimed at preventing HIV transmission from the infected to the uninfected partner, including explicit discussion and clarification of any misconceptions regarding HIV transmission risk associated with specific sexual or needle-sharing activities. In addition, many HIV-discordant couples benefit from ongoing HIV prevention counseling aimed at personal risk reduction or from couples counseling that teaches safe sexual practices and proper condom use. Little evidence exists to conclusively support or refute whether simultaneous infection with $\geq$2 subtypes of HIV is likely to occur or, if it does, whether it is associated with more aggressive or resistant disease. Researchers are divided on the value of recommending consistent condom use to prevent HIV sequelae for mutually monogamous, HIV-infected partners.
- Health-care workers after an occupational exposure. After an occupational exposure, health-care workers should use measures to prevent transmission during the follow-up period. HIV-exposed health-care workers should be advised that, although HIV is infrequently transmitted through an occupational exposure, they should abstain from sex or use condoms and avoid pregnancy until they receive a negative follow-up test result. In addition, they should not donate blood, plasma, organs, tissue, or semen; if a woman is breast-feeding, she should consider discontinuing. Health-care workers should also be advised of the rationale for postexposure prophylaxis, the risk for occupationally acquired HIV infection from the exposure, the limitations of current knowledge of the efficacy of antiretroviral therapy when used as postexposure prophylaxis, the toxicity of the drugs involved, and the need for postexposure follow-up (including HIV testing), regardless of whether antiretroviral therapy is taken. Further guidance on occupational HIV exposure is available.
- Participants in HIV vaccine trials. HIV-vaccine-induced antibodies may be detected by current HIV tests and may cause a false-positive result. Trial participants should be advised that HIV counseling, testing, and referral best provided at the vaccine trial sites, the vaccine is of unknown efficacy, and HIV risk behavior can result in their becoming HIV-infected (see the section titled "Positive Test Results").

## Addressing Barriers to HIV Prevention Counseling

Several factors can prevent provision of high-quality HIV prevention counseling, including unavailability of trained prevention counselors at the setting in which the HIV test was conducted, client reluctance, and low rates of client return for test results. Recommended strategies for addressing these common barriers include (a) providing counseling on-site, (b) enhancing client acceptance of counseling by examining and improving the counseling provided, and (c) considering alternate counseling methods.

## Provide On-Site Counseling

Cost, lack, or turnover of trained staff members and space constraints are barriers to providing HIV prevention counseling. However, given the proven efficacy of prevention counseling models, in settings where HIV prevalence is high or the population served is at increased risk, the ability to provide such counseling on-site is a high priority, and efforts should be made to address and remove barriers to providing HIV prevention counseling on-site. Health educators or other auxiliary staff members trained to discuss preventive activities such as healthy eating, prenatal education, or smoking cessation could, if adequately trained, be effective HIV prevention counselors. In the interim, alternative resources should be identified, and clearly defined referrals should be made to settings that can provide high-quality prevention counseling for clients at increased HIV risk. Systems to ensure that referrals are completed should be established (see the section titled "HIV Referral").

## Enhance Client Acceptance of HIV Prevention Counseling

Clients who agree to HIV testing but decline HIV prevention counseling often report they lack time or already are aware of HIV transmission modes. However, experienced counselors report that clients mainly refuse counseling because they do not perceive the service to be personally beneficial (Technical Expert Panel Review of Centers for Disease Control and Prevention HIV Counseling, Testing, and Referral Guidelines; February 18 to 19, 1999; Atlanta, Georgia). These counselors believe that most of these clients are concerned about a specific risk, which they would be willing to explore if the counseling seemed useful. Three of the most commonly reported barriers to the perceived usefulness of counseling are the type of counseling provided, how it is recommended, and the setting of the counseling. In settings where many clients are declining counseling, these barriers and others should be examined. The counseling might be providing information only rather than addressing personal risks. Counselors might not be offering counseling in ways appropriate to the client's culture, language, sex, sexual orientation, age, or developmental level. The setting might inhibit open discussion of risk (e.g., some outreach settings are not private). Counseling skills (e.g., attentive listening, use of open-ended questions) that allow clients to participate might have been overlooked. Even when clients at increased risk refuse counseling, use of 1 to 2 open-ended questions that urge clients to examine their personal situations could prompt personal exploration of risk (e.g., "What were your concerns that led you to decide to get tested today?").

## Consider Alternative Methods for HIV Prevention Counseling

HIV prevention counseling models proven effective have all used face-to-face (individual or group) encounters between counselor and client and involved $\geq$2 brief sessions. Thus, face-to-face prevention counseling is preferred for clients at increased HIV risk. Most HIV test sites use an enzyme immunoassay (EIA) and confirmatory test algorithm that requires several days for final results. The return visit for test result offers an opportunity to continue prevention counseling in a second, face-to-face meeting. However, in some settings (e.g., sexually-transmitted-disease clinics, managed care organizations, and other private settings), many clients do not return for their results. In such settings, providers

can adopt strategies that increase clients' receipt of test results, and counseling strategies might need to be adapted.

- Telephone Counseling. Limited studies among sexually-transmitted-diseases clinic clients at lower risk indicated that substantially more clients learned their HIV infection status when negative test results were provided by telephone rather than in person. Although home sample collection provides a precedent for providing counseling by telephone to persons with either negative or positive HIV test results, the efficacy of telephone counseling in reducing HIV risk behaviors or the number of new HIV infections has not been studied. One study indicated that telephone notification of positive results was associated with delay in linkage to care. However, not learning positive test results at all guarantees a delay in linkage to care. Many specialists recommend that provision of HIV test results and prevention counseling by telephone be limited to clients whose results are negative (Technical Expert Panel Review of Centers for Disease Control and Prevention HIV Counseling, Testing, and Referral Guidelines; February 18 to 19, 1999; Atlanta, Georgia). Also, given the known risk reduction benefits of face-to-face counseling, lack of efficacy data on telephone counseling, and concerns regarding disinhibition (e.g., "since my test result is negative, whatever risks I am taking now may be okay"), telephone counseling should be limited to clients without known ongoing HIV risk behaviors (e.g., unprotected sex or needle sharing with an HIV-infected [or status unknown] partner).
- Single-Session Prevention Counseling with Rapid Testing. Rapid tests allow clients to receive their HIV test results the same day. This process could reduce the number of clients receiving two prevention counseling sessions. Studies of the efficacy of single HIV prevention counseling sessions for use with a rapid test are under way. Although some single-session counseling protocols have been successfully implemented in busy clinics and are well-accepted by most clients, how well a single counseling session reduces risk behaviors or the number of new HIV infections is unknown. A counseling protocol for use with a rapid test is being studied; information is available at the Centers for Disease Control and Prevention Web site. For clients with identified risk behaviors, referral or rescheduling for ongoing counseling should be considered.

## Ensuring High-Quality HIV Prevention Counseling

All counseling, testing, and referral providers should conduct routine, periodic assessments for quality assurance to ensure that the counseling being provided includes the recommended, essential counseling elements.

Supervisors must be aware of HIV prevention counseling goals and necessary counselor skills. Supervisor and administrator support of HIV counseling models that focus on personal risk reduction (distinct from provision of information) is critical to effective counseling. Quality assurance for counseling should contain the following elements:

- Training and continuing education. Basic training in the use of $\geq$1 of the interactive HIV prevention counseling models aimed at personal risk reduction is recommended for counselors and supervisors. Counselors should know the communities they serve and the available referral opportunities. They also

might benefit from formal training on (a) transmission and prevention of HIV and other sexually transmitted and blood-borne diseases, (b) the natural history of HIV, (c) recognition and treatment of opportunistic infections, (d) new therapeutic agents used to treat HIV and AIDS, (e) partner counseling and referral services [PCRS], (f) prevention case management, and (g) other HIV prevention and support services available in the community (e.g., services related to substance abuse assessment, cultural competence, adolescent concerns, domestic abuse, and health concerns for gay or lesbian clients). Additional training in specific counseling skills is also warranted (e.g., training on how to facilitate groups for counselors conducting group sessions). For training opportunities, providers or supervisors can contact their state health department's HIV/AIDS program office.

- Supervisor observation and immediate feedback to counselors. Direct observation of counseling sessions can help ensure that objectives are being met. Supervisors can perform this task periodically (with client consent). Sessions might also be audiotaped (with client consent), or counseling can be demonstrated through role-play scenarios between the counselor and supervisor. Observation and feedback should be structured, and the outcome should be constructive, not punitive. Supervisors should support positive elements of the prevention counseling session and provide specific, constructive comments regarding content areas needing improvement. Observation and feedback should be conducted regularly for routine counseling. Staff discomfort with observation typically wanes over time; many counselors report that the sessions are useful in enhancing skills. When observation is offered routinely, clients seldom refuse to participate. A suggested time frame for routine, direct observation of an HIV prevention counselor by the supervisor is twice monthly for the first 6 months, monthly for the second 6 months, and quarterly for counselors with >1 year of experience. After observation, supervisors should provide feedback to counselors quickly, preferably the same week. Observation and feedback forms used in research studies of client-centered HIV prevention counseling are available at the Centers for Disease Control and Prevention Web site.
- Periodic evaluation of physical space, client flow, and time concerns. Counseling sessions should be conducted in a private space where discussion cannot be overheard. Clients should not wait for long periods between testing and counseling, and information could be provided during waiting times (e.g., through videos). Periodic time-flow analyses or client surveys can be used to evaluate adequacy of space, client flow, and length of waiting period.
- Periodic counselor or client satisfaction evaluations. Evaluations of client satisfaction can ensure that counseling meets client needs. These evaluations also can provide important feedback to counselors who otherwise might not see the benefits of what they do. Evaluations can be brief. Surveys should address whether specific counseling goals were met, the type of interaction (e.g., "who talked more, the counselor or the client?"), and, when applicable, specifics of development of the risk-reduction plan (e.g., "what was the behavior change step that you agreed to work on?"). Linking client and counselor descriptions of a particular session might be useful. Conducting such evaluations only occasionally (e.g., for 1 to 2 weeks once or twice a year) decreases the programmatic burden and is probably sufficient to identify problems. For more information, see the section titled "Quality Assurance and Evaluation of HIV Counseling, Testing, and Referral Services."
- Case conferences. Regularly scheduled meetings of counselors allow supervisors to understand counselors' skills and areas that need improvement

and can help counselors learn techniques from their colleagues. Case conferences are an opportunity for counselors to discuss specific or problematic questions asked by clients, allowing providers to better understand the concerns facing clients who are HIV-infected or at increased risk for HIV. Case conferences can help offset counselor fatigue and "burn out" by providing a positive outlet for dealing with difficult situations. Discussion might focus on a hard-to-address client or specific elements (e.g., developing acceptable and practical risk-reduction plans with clients who deny the magnitude of their HIV risk). Frequency of case conferences should be balanced with client volume, with efforts made to meet at least monthly.

## HIV Testing

### Characteristics and Applications of HIV Test Technologies

Only U.S. Food and Drug Administration (FDA)-approved HIV tests should be used for diagnostic purposes. Routine screening in the United States for HIV-2 and HIV-1 group O infections is not generally recommended unless geographic, behavioral, or clinical information indicates that infection with these strains might be present. Several HIV test technologies have been approved by the U.S. Food and Drug Administration for diagnostic use in the United States. These tests enable testing of different fluids (i.e., whole blood, serum, plasma, oral fluid, and urine). Refer to the original guideline document for the table titled "Performance Attributes and Potential Applications of HIV Test Technologies Approved by the U.S. Food and Drug Administration (FDA) for Diagnostic Use." The available technologies:

- Enable specimen collection procedures that are less invasive and more acceptable than venipuncture, thus helping expand HIV testing into nontraditional settings (with home sample collection tests, oral fluid tests, and urine-based tests)
- Enable provision of HIV test results during a single visit at the time of testing (with rapid tests)
- Increase the convenience of HIV testing (with home sample collection tests).

The decision to adopt a particular test technology in a clinical or nontraditional setting should be based on several factors, including:

- Accuracy of the test
- Client preferences and acceptability
- Likelihood of client returning for results
- Cost and mechanism for provider reimbursement
- Ease of sample collection
- Complexity of laboratory services required for the test
- Availability of trained personnel
- U.S. Food and Drug Administration (FDA) approval of the test

### Home Testing Versus Home Sample Collection

The U.S. Food and Drug Administration has not approved home-use HIV test kits, which allow consumers to purchase a test kit, collect a sample in private, and interpret their own HIV test results in a few minutes. The U.S. Federal Trade Commission has warned that some home-use HIV test kits, many of which are

available on the Internet and in the "gray" market (i.e., unauthorized imports), supply inaccurate results. These tests are different from U.S. Food and Drug Administration-approved home sample collection kits, which allow consumers to purchase test kits, collect a sample in private, send the sample to a laboratory for testing, and telephone for their HIV test result, counseling, and referral.

### HIV-2 and HIV-1 Group O Infections

Although most HIV infections in the United States are of HIV-1 group B subtype, current enzyme immunoassays (EIAs) can accurately identify infections with nearly all non-B subtypes and many infections with group O HIV subtypes. Infections with HIV-2 and HIV-1 group O are rare in the United States, and routine screening for these subtypes is not generally recommended as part of diagnostic testing except in areas where several such infections have been identified. Routine screening for HIV-2 might be appropriate in certain populations where potential risk for HIV-2 infection is higher (e.g., in areas where West African immigrants have settled). Since June 1992, the U.S. Food and Drug Administration has recommended routine screening for antibody to HIV-2 (in addition to HIV-1) for all blood and plasma donations. Clients with clinical, epidemiologic, or laboratory history that suggests HIV infection and negative or indeterminate HIV-1 screening tests should receive further diagnostic testing to rule out HIV infection, potentially including testing for HIV-1 non-B subtypes and HIV-2.

### Other Test Uses

Viral load and HIV-1 p24 antigen assays are not intended for routine diagnosis but could be used in clinical management of HIV-infected persons in conjunction with clinical signs and symptoms and other laboratory markers of disease progression. Although HIV-1 p24 antigen assays are used for routine screening in blood and plasma centers, routine use for diagnosing HIV infection has been discouraged because the estimated average time from detection of p24 antigen to detection of HIV antibody by standard enzyme immunoassay is 6 days, and not all recently infected persons have detectable levels of p24 antigen.

## Interpreting HIV Test Results

### Standard Testing Algorithm

HIV-1 testing consists of initial screening with an enzyme immunoassay to detect antibodies to HIV-1. Specimens with a nonreactive result from the initial enzyme immunoassay (EIA) are considered HIV-negative unless new exposure to an infected partner or partner of unknown HIV status has occurred. Specimens with a reactive enzyme immunoassay result are retested in duplicate. If the result of either duplicate test is reactive, the specimen is reported as repeatedly reactive and undergoes confirmatory testing with a more specific supplemental test (e.g., Western blot or, less commonly, an immunofluorescence assay [IFA]). Only specimens that are repeatedly reactive by enzyme immunoassay and positive by immunofluorescence assay or reactive by Western blot are considered HIV-positive and indicative of HIV infection. Specimens that are repeatedly enzyme immunoassay reactive occasionally provide an indeterminate Western blot result, which might represent either an incomplete antibody response to HIV in

specimens from infected persons or nonspecific reactions in specimens from uninfected persons. Although immunofluororescence assay can be used to resolve an indeterminate Western blot sample, this assay is not widely used. Generally, a second specimen should be collected ≥1 month later and retested for persons with indeterminate Western blot results. Although much less commonly available, nucleic acid testing (e.g., viral ribonucleic acid [RNA] or proviral deoxyribonucleic acid [DNA] amplification method) could also help resolve an initial indeterminate Western blot in certain situations. A small number of tested specimens might provide inconclusive results because of insufficient quantity of specimen for the screening or confirmatory tests. In these situations, a second specimen should be collected and tested for HIV infection.

### Modified Testing Algorithms

The U.S. Food and Drug Administration has licensed only one rapid test, but modified testing algorithms are anticipated when additional rapid HIV tests are approved. If ≥2 sensitive and specific rapid HIV tests became available, one positive rapid test could be confirmed with a different rapid test. This combination has provided positive predictive value compared with the enzyme immunoassay/Western blot or immunofluorescence assay algorithm. However, no such algorithms have been adequately assessed or approved for diagnostic use in the United States.

### Positive HIV Test Results

An HIV test should be considered positive only after screening and confirmatory tests are reactive. A confirmed positive test result indicates that a person has been infected with HIV. False-positive results when both screening and confirmatory tests are reactive are rare. However, the possibility of a mislabeled sample or laboratory error must be considered, especially for a client with no identifiable risk for HIV infection. HIV-vaccine-induced antibodies may be detected by current tests and may cause a false-positive result. Persons whose test results are HIV-positive and who are identified as vaccine trial participants should be encouraged to contact or return to their trial site or an associated trial site for HIV counseling, testing, and referral services.

### Negative HIV Test Results

Because a negative test result likely indicates absence of HIV infection (i.e., high negative predictive value), a negative test need not be repeated in clients with no new exposure in settings with low HIV prevalence. For clients with a recent history of known or possible exposure to HIV who are tested before they could develop detectable antibodies, the possibility of HIV infection cannot be excluded without follow-up testing. A false negative result also should be considered in persons with a negative HIV-1 test who have clinical symptoms suggesting HIV-1 infection or AIDS. Additional testing for HIV-2 and HIV-1 group O infection might be appropriate for these persons.

### Indeterminate HIV Test Results

Most persons with an initial indeterminate Western blot result who are infected with HIV-1 will develop detectable HIV antibody within 1 month. Thus, clients with

an initial indeterminate Western blot result should be retested for HIV-1 infection ≥1 month later. Persons with continued indeterminate Western blot results after 1 month are unlikely to be HIV-infected and should be counseled as though they are not infected unless recent HIV exposure is suspected.

Nucleic acid tests for HIV deoxyribonucleic acid or ribonucleic acid exist, but are not approved by the U.S. Food and Drug Administration for diagnostic purposes and are not generally recommended for resolving indeterminate Western blot results. However, in consultation with clinical and laboratory specialists, nucleic acid testing (if available) might also be useful for determining infection status among persons with an initial indeterminate Western blot result.

### Informing Clients of Test Results

Because low rates of return for test results occur in many settings offering HIV counseling, testing, and referral, providers should work to ensure that clients tested for HIV infection receive their test results, particularly HIV-infected clients who might benefit from earlier entry into care and initiation of antiretroviral therapy. Reducing barriers to testing can maximize the number and proportion of persons tested for HIV who receive their test results in a timely manner (see the section titled "Addressing Barriers to HIV Testing"). Adoption of new HIV test technologies and alternative methods of providing HIV-negative test results should be considered when face-to-face rates of return for test results are low. Strict confidentiality of the receipt of the HIV test and the HIV test result must be maintained, regardless of the method used. Providers unable to locate clients who do not return for test results should seek support from their local or state health department.

Because knowledge of HIV status is a critical HIV prevention strategy and essential for entry into care, providers should stress to clients the importance of returning to receive their test results and establish a plan for doing so with the client. Reminder systems might be useful. Using alternate HIV test technologies might increase the percentage of tested persons who learn their HIV status.

### Providing Test Results by Telephone

Many clinicians routinely notify clients of negative test results for various diseases and conditions by means other than face-to-face (e.g., by telephone). They also ask clients to return to discuss positive test results that might indicate potential life-threatening illnesses. This strategy can also be applied, under limited circumstances, to notifying clients of their HIV test results. Face-to-face provision of HIV test results is strongly encouraged for HIV-infected clients and HIV-uninfected clients at increased risk who might benefit from HIV prevention counseling and referral to medical, preventive, and support services. Providing uninfected clients who are not at increased risk the option of receiving HIV test results and counseling by telephone -- with the understanding that provider assurance of client confidentiality is of paramount importance -- might be appropriate. Limited research indicates that offering clients the option of contacting the provider by telephone to receive negative HIV results might increase rates of receipt of results, satisfy client preferences for options, and preserve setting resources without apparent adverse consequences. Although no published research exists regarding use of telephones for providing positive HIV

test results with most HIV test technologies, limited experience exists on using this method to provide HIV-positive test results for home sample collection testing.

### Providing Test Results During the Initial Visit Through Rapid Tests

More clients receive their HIV test results with rapid tests because results can be provided at the testing visit. Rapid test technology could be useful in urgent medical circumstances (e.g., when decisions must be made regarding postexposure prophylaxis) and in nontraditional settings with low return rates (e.g., community-based or outreach settings).

During the initial visit, the provider can definitively tell clients who have had a single rapid HIV test with negative results that they are not infected, except when retesting might be indicated because of recent known or possible exposure to HIV. A reactive rapid HIV test result should be considered preliminary until the completion of confirmatory testing, and results should be carefully communicated to the client because of the possibility of a false-positive result.

The likelihood that a positive screening test truly indicates the presence of HIV infection decreases as HIV prevalence in the tested population becomes lower. Therefore, false-positive HIV test results are more likely in settings where the tested population prevalence is lower than in settings where the tested population prevalence is higher. When a preliminary, positive rapid test is explained to clients, phrases like "a good chance of being infected" or "very likely infected" can be used to indicate the likelihood of HIV infection and qualified based on the HIV prevalence in the setting and the client's individual risk. Further testing is always required to confirm a reactive screening test result.

### Follow-up Testing in Clients with Negative HIV Test Results

A negative HIV test usually indicates the absence of HIV infection. Because recent infection cannot be excluded without follow-up testing (see the section titled "Negative HIV Test Results"), the appropriate timing and frequency for follow-up testing among clients with negative HIV test results has not been firmly established. Providers should consider the following factors related to individual client needs when recommending the timing and frequency for follow-up HIV testing:

- Timing of the last potential exposure
- Probability of HIV infection given type of exposure
- Presence or likelihood of ongoing risk behavior
- Likelihood of returning for follow-up HIV testing, prevention counseling, and referral
- Client anxiety
- Provider and client relationship.
- Resource constraints.

### Recent Exposure

Follow-up testing might be appropriate for clients who have negative test results but who have not had time to develop detectable antibody after a recent documented occupational or nonoccupational (sexual or needle-sharing) exposure to HIV-infected persons or persons at increased risk for HIV with unknown HIV status. The timing of follow-up testing should provide assurance that the exposure did not lead to infection. Follow-up testing should be conducted in a timely manner so clients identified as HIV-infected can receive appropriate antiretroviral treatment and prevention and support services as soon as possible.

### Single Possible or Known Exposure

Most infected persons will develop detectable HIV antibody within 3 months of exposure. If the initial negative HIV test was conducted within the first 3 months after exposure, repeat testing should be considered $\geq$3 months after the exposure occurred to account for the possibility of a false-negative result. If the follow-up test is nonreactive, the client is likely not HIV-infected. However, if the client was exposed to a known HIV-infected person or if provider or client concern remains, a second repeat test might be considered $\geq$6 months from the exposure. Rare cases of seroconversion 6-12 months after known exposure have been reported. Extended follow-up testing beyond 6 months after exposure to account for possible delayed seroconversion is not generally recommended and should be based on clinical judgment and individual clients needs.

### Ongoing Exposure

Persons with continued HIV risk behavior pose a special challenge for follow-up testing. In some settings, clients with ongoing risk represent a substantial proportion of those receiving HIV counseling, testing, and referral. In most circumstances, follow-up HIV testing should be recommended periodically for clients with ongoing risk behavior. Follow-up testing would monitor the client's HIV status, but also promote continued client contact, opportunities for HIV prevention counseling (see the section titled "Additional Counseling Considerations for Special Situations"), and referral to additional preventive and support services.

### No Identifiable Risk

In general, persons with no recent identifiable risk for HIV infection should receive additional HIV prevention counseling and follow-up testing when requested. Efforts should be made to understand why these clients repeatedly seek follow-up testing. These clients should be considered for in-depth prevention counseling and referral to support services, where appropriate.

### Special Considerations

General recommendations for follow-up testing might not be applicable in all circumstances. In certain circumstances (e.g., when persons are simultaneously exposed to hepatitis C virus and HIV and when persons have received HIV vaccines), guidance should be provided only after consultation with specialists.

### Addressing Barriers to HIV Testing

Knowledge of HIV infection status can benefit the health of individual persons and the community. Thus, HIV testing should be as convenient as possible to promote client knowledge of HIV infection status. Efforts should be made to remove or lower barriers to HIV testing by ensuring that

- Testing is accessible, available, and responsive to client and community needs and priorities
- Anonymous and confidential HIV testing are available;
- The testing process considers the client's culture, language, sex, sexual orientation, age, and developmental level
- Confidentiality is maintained (see the section titled "Principles of HIV Counseling, Testing, and Referral").

Acceptance of HIV testing is reportedly lower when clients have been tested previously and are fearful of their ability to cope with their test results. Testing is more likely to be accepted when:

- Clients perceive their own HIV risk and acknowledge behaviors placing them at increased risk
- Testing is voluntary and routinely offered to clients rather than clients having to request it
- Protections for client confidentiality are in place
- Anonymous testing is available
- Alternate HIV test technologies are offered to clients
- Providers recommend testing as part of appropriate medical care
- Providers and clients perceive HIV counseling and testing to be beneficial for early diagnosis and prevention purposes.

### Ensuring High-Quality Testing

Testing activities should be coordinated with state and local laboratories to ensure high-quality HIV testing through proper specimen collection, storage, and transport. Laboratory errors most often occur in the preanalytic (i.e., specimen collection, labeling, transporting, processing, and storing) and postanalytic steps of testing (i.e., results validation and reporting) rather than during the test itself. Laboratories performing HIV testing must be enrolled in proficiency testing programs and conduct activities in accordance with regulatory standards outlined by the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Many states have additional licensing requirements for laboratories conducting diagnostic HIV testing.

## HIV Referral

### Definition of Referral

In the context of HIV prevention counseling and testing, referral is the process by which immediate client needs for care and supportive services are assessed and prioritized and clients are provided with assistance (e.g., setting up appointments, providing transportation) in accessing services. Referral should also include follow-up efforts necessary to facilitate initial contact with care and support service providers.

In this context, referral does not include ongoing support or management of the referral or case management. Case management is generally characterized by an ongoing relationship with a client that includes comprehensive assessment of medical and psychosocial support needs, development of a formal plan to address needs, substantial assistance in accessing referral services, and monitoring of service delivery.

### Typical Referral Needs

Clients should be referred to services that are responsive to their priority needs and appropriate to their culture, language, sex, sexual orientation, age, and developmental level. Examples of these services include:

- Prevention case management. Clients with multiple and complex needs that affect their ability to adopt and sustain behaviors to reduce their risk for transmitting or acquiring HIV should receive or be referred for prevention case management services, including ongoing prevention counseling. Prevention case management can help coordinate diverse referral and follow-up concerns.
- Medical evaluation, care, and treatment. HIV-infected clients should receive or be referred to medical services that address their HIV infection (including evaluation of immune system function and screening, treatment, and prevention of opportunistic infections). Screening and prophylaxis for opportunistic infections and related HIV-conditions (e.g., cervical cancer) are important for HIV-infected persons. In addition, coinfection with HIV and communicable diseases (e.g., tuberculosis, sexually transmitted diseases, and hepatitis) can, if untreated, pose a risk to susceptible community members. Thus, providers of HIV testing should be familiar with appropriate screening tests (e.g., tuberculosis), vaccines (e.g., hepatitis A and B), sexually transmitted diseases and prophylactic tuberculosis treatment, and clinical evaluation for active tuberculosis disease to ensure that these communicable diseases are identified early and appropriate clinical referrals are made, even if clients forego outpatient HIV treatment.
- Partner counseling and referral services. Persons with HIV-positive test results should receive or be referred to services to help them notify their sex or injection drug-equipment-sharing partners or spouses regarding their exposure to HIV and how to access counseling, testing, and referral. Guidelines for partner counseling and referral services (PCRS) are available.
- Reproductive health services. Female clients who are pregnant or of childbearing age should receive or be referred to reproductive health services. HIV-infected pregnant women should be referred to providers who can provide prevention counseling and education, initiate medical therapy to prevent perinatal transmission, and provide appropriate care based on established treatment guidelines (see the related guidelines titled "Revised Recommendations for HIV Screening of Pregnant Women" [MMWR Recomm Rep 2001 Nov 9;50(RR-19):59-86; a related National Guideline Clearinghouse (NGC) Guideline Summary is also available]).
- Drug or alcohol prevention and treatment. Clients who abuse drugs or alcohol should receive or be referred to substance or alcohol abuse prevention and treatment services.

- Mental health services. Clients who have mental illness, developmental disability, or difficulty coping with HIV diagnosis or HIV-related conditions should receive or be referred to appropriate mental health services.
- Legal services. Clients who test positive should be referred to legal services as soon as possible after learning their test result for counseling on how to prevent discrimination in employment, housing, and public accommodation by only disclosing their status to those who have a legal need to know.
- Sexually transmitted diseases screening and care. Clients who are HIV-infected or at increased risk for HIV are at risk for other sexually transmitted diseases and should receive or be referred for sexually transmitted diseases screening and treatment.
- Screening and treatment for viral hepatitis. Many clients who are HIV-infected or at increased risk for HIV are at increased risk for acquiring viral hepatitis (A, B, and C). Men who have sex with men and injection-drug users should be vaccinated for hepatitis A. All clients without a history of hepatitis B infection or vaccination should be tested for hepatitis B, and if not infected, should receive or be referred for hepatitis B vaccination. In addition, clients who inject drugs should be routinely recommended testing for hepatitis C. All clients who are infected with hepatitis viruses should be referred for appropriate treatment. Further guidance is available.
- Other services. Clients might have multiple needs that can be addressed through other HIV prevention and support services (e.g., assistance with housing, food, employment, transportation, child care, domestic violence, and legal services). Addressing these needs can help clients access and accept medical services and adopt and maintain behaviors to reduce risk for HIV transmission and acquisition. Clients should receive referrals as appropriate for identified needs.

### Implement and Manage Referral Services

Clients should receive help accessing and completing referrals, and completion of referrals should be verified. In the context of HIV prevention counseling and testing, the following elements should be considered essential to the development and delivery of referral services.

### Assess Client Referral Needs

Providers should consult with the client to identify essential factors that (a) are likely to influence the client's ability to adopt or sustain behaviors to reduce risk for HIV transmission or acquisition or (b) promote health and prevent disease progression. Assessment should include examination of the client's willingness and ability to accept and complete a referral. Service referrals that match the client's self-identified priority needs are more likely to be successfully completed than those that do not. Priority should be placed on ensuring that HIV-infected clients are assessed for referral needs related to medical care, partner counseling and referral services, and prevention and support services aimed at reducing the risk for further transmission of HIV. When a provider cannot make appropriate referrals or when client needs are complex, clients should be referred to a case management system.

### Plan the Referral

Referral services should be responsive to clients' needs and priorities and appropriate to their culture, language, sex, sexual orientation, age, and developmental level. In consultation with clients, providers should assess and address any factors that make completing the referral difficult (e.g., lack of transportation or child care, work schedule, cost). Research has indicated that referrals are more likely to be completed if services are easily accessible to clients.

### Help Clients Access Referral Services

Clients should receive information necessary to successfully access the referral service (e.g., contact name, eligibility requirements, location, hours of operation, telephone number). Research has indicated that providing assistance (e.g., setting an appointment, addressing transportation needs) for some clients promotes completion of referrals. Clients must give consent before identifying information to help complete the referral can be shared. Outreach workers and peer counselors/educators can be an important and effective resource to help clients identify needs and plan successful referrals. Referrals are more likely to be completed after multiple contacts with outreach workers.

### Document Referral and Follow-Up

Providers should assess and document whether the client accessed the referral services. If the client did not, the provider should determine why; if the client did, the provider should determine the client's degree of satisfaction. If the services were unsatisfactory, the provider should offer additional or different referrals. Documentation of referrals made, the status of those referrals, and client satisfaction with referrals should help providers better meet the needs of clients. Information obtained through follow-up of referrals can identify barriers to completing the referral, responsiveness of referral services in addressing client needs, and gaps in the referral system.

### Ensure High-Quality Referral Services

Providers of referral services should know and understand the service needs of their clients, be aware of available community resources, and be able to provide services in a manner appropriate to the clients' culture, language, sex, sexual orientation, age, and developmental level, given local service system limitations.

### Education and Support of Staff Members

Staff members providing referral services must understand client needs, have skills and resources to address these needs, have authority to help the client procure services, and be able to advocate for clients.

Training and Education. Providers should ensure that staff members receive adequate training and continuing education to implement and manage referrals. Training and education should address resources available and methods for managing referrals, as well as promote understanding of factors likely to influence the client's ability and willingness to use a referral service (e.g., readiness to accept the service, competing priorities, financial resources). Referrals are more

likely to be completed when a provider is able to correctly evaluate a client's readiness to adopt risk-reducing behaviors. Research has indicated that cross-training increases knowledge and understanding of community resources among providers and can indicate gaps in services.

Authority. Staff members providing referrals must have the authority necessary to accomplish a referral. Supervisors must ensure that staff members understand referral policy and protocol and have the necessary support to provide referrals. This requires the authority of one provider to refer to another (e.g., through memoranda of agreement) or to obtain client consent for release of medical or other personal information.

Advocacy. Staff members who negotiate referrals must possess knowledge and skills to advocate for clients. Such advocacy can help clients obtain services by mediating barriers to access to services and promoting an environment in which providers are better informed regarding the needs and priorities of their clients.

### Provider Coordination and Collaboration

Providers should develop and maintain strong working relationships with other providers and agencies that might be able to provide needed services. Providers who offer HIV prevention counseling and testing but not a full range of medical and psychosocial support services should develop direct, clearly delineated arrangements with other providers who can offer needed services. Coordination and collaboration promotes a shared understanding of the specific medical and psychosocial needs of clients requiring services, current resources available to address these needs, and gaps in resources.

Memoranda of agreement or other forms of formal agreement are useful in outlining provider/agency relationships and delineating roles and responsibilities of collaborating providers in managing referrals. When confidential client information is shared between coordinating providers, such formal agreements are essential. These agreements should be reviewed periodically and modified as appropriate.

### Referral Resources

Knowledge of available support services is essential for successful referrals. When referral resources are not available locally, providers should identify appropriate resources and link clients with them. A resource guide should be developed and maintained to help staff members make appropriate referrals (see Box 7 titled "Contents of a Resource Referral Guide" in the original guideline document). Information regarding community resources can be obtained from local health planning councils, consortia, and community planning groups. Local, state, and national HIV/AIDS information hotlines or Web sites (e.g., National Prevention Information Network [NPIN]), community-based health and human service providers, and state and local public health departments can also provide information.

## HIV Counseling, Testing, and Referral Services in Nontraditional Settings

Counseling, testing, and referral should be provided in community-based and outreach settings as well as clinical settings. Data from publicly supported counseling, testing, and referral programs have indicated that doing so could promote use of these services by persons at increased risk for HIV. When HIV counseling, testing, and referral are not readily available, accessible, or acceptable, persons at increased risk might not take advantage of them. Expanding counseling, testing, and referral into nontraditional settings can be accomplished through partnership with community-based service providers and use of new, U.S. Food and Drug Administration-approved HIV test technologies that offer portability, less-invasive sample collection, less-complex sample collection and processing, and reduced biohazard. To ensure effective counseling, testing, and referral that is responsive to client needs, providers should develop and implement written quality assurance protocols and procedures specifically for services provided in nontraditional settings.

### Privacy and Confidentiality

Ensuring clients' privacy and confidentiality during counseling, testing, and referral is essential, but could present unique challenges in some nontraditional settings. Confidentiality can more easily be breached in settings where clients and providers can be seen or heard by others. Suggested strategies for maintaining privacy and confidentiality in nontraditional settings include the following:

- Use a separated area in a mobile van
- Use rooms with locking doors
- Mark a specific room with a "do not disturb" or "occupied" sign
- Designate an area in the setting that provides physical privacy
- In parks and similar locations, seek areas with as much privacy as possible
- Provide counseling and testing services in the client's home or other secure setting
- Have clients return to the setting to receive test results and counseling and referral.

### Informed Consent

Staff members providing counseling, testing, and referral services should be sensitive to barriers that can interfere with obtaining true informed consent, including alcohol and drug use, mental illness, and peer pressure in venues where persons congregate or socialize. Suggested strategies for obtaining informed consent in nontraditional settings include the following:

- Schedule an appointment to test at a later date/time
- Follow up at a later time with the client if contact information is available
- Read the informed consent form to the client
- Use verbal prompts to ensure that the client understands information in the informed consent form.

### Counseling

Staff members working in community-based and other nontraditional settings should know and use risk-screening strategies to determine whether HIV prevention counseling should be recommended. Staff members should be trained

in HIV prevention counseling or other approaches aimed at personal HIV risk reduction. When appropriate (e.g., among injection-drug users [IDUs]), information regarding other sexually transmitted diseases and blood-borne diseases should be incorporated into the counseling sessions.

### Testing

The decision to offer HIV testing in nontraditional settings should be based on several factors, including availability of resources and feasibility of providing test results and follow-up. In some cases, referral to other providers is appropriate. The selection of a specific HIV test technology should be based on logistical issues (e.g., field conditions related to collection, transport, and storage of specimens; worker safety; and the likelihood that clients will receive HIV test results). Providers must understand the extent to which field conditions can affect specimens (e.g., extreme temperatures or time lapse from collection to processing). Test specimens should be collected, stored, and transported according to manufacturer instructions.

### Provision of Test Results

Clear protocols for provision of test results and prevention counseling should be developed. The following strategies might be useful in ensuring the provision of results in nontraditional settings:

- Provide a telephone number that clients can call to receive test results
- Make an appointment with the client at the time of testing to receive results
- Provide incentives (e.g., food certificates, hygiene kits, food)
- Return to a site on a regularly scheduled basis
- Provide reminders when contact information is available

### Referral

Staff members working in community-based and outreach settings should be trained to implement and manage referrals. Providers should establish appropriate collaborative relationships for referrals. Arranging for partner counseling and referral services staff members or case managers to be available to clients at the time test results are provided might help promote referral.

### Record Keeping

Maintaining the confidentiality of client records is critical. Providers should develop written protocols for record keeping that address transport of client records to and from outreach venues. Strategies to maintain confidentiality of client records in nontraditional settings include the following:

- Return all client records to the office immediately after the counseling, testing, and referral session
- Use codes or unique identifiers rather than client names
- Store all records in a secured area (e.g., locked file drawers)
- Provide option of anonymous counseling and testing as well as confidential counseling and testing

- Verify identity of client (e.g., match client signature with that provided for informed consent or check identification card) when providing test results
- Store paperwork in a lockbox while in outreach settings
- Password protect and encrypt electronically stored client records.

Where allowed by state/local statute, clients can choose anonymous HIV testing. Procedures to ensure client anonymity (i.e., no indication of testing in the client's record and no recording of personal identifying information on laboratory requests) should be developed. Even when staff members providing counseling, testing, and referral services know the client (including name and locating information) from other activities, the client's right to be tested anonymously should be protected.

Staff Safety

Providing services in outreach settings (e.g., bars, parks) might compromise staff safety, which must be considered in development of outreach protocols. Appropriate training and precautions (e.g., working in teams) should be developed in planning services in nontraditional settings.

### CLINICAL ALGORITHM(S)

Algorithms are provided for:

1. Counseling, testing, and referral in settings serving populations at increased behavioral or clinical HIV risk.
2. Counseling, testing, and referral in low prevalence settings.
3. Counseling, testing, and referral in high prevalence settings.

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Advances in HIV prevention and medical treatment increase the importance of HIV counseling, referral, and testing services. Prevention counseling and knowledge of HIV status can help persons who are HIV-infected or at increased risk for HIV infection reduce their risk for transmitting or acquiring HIV infection. Referral can help persons access relevant medical, preventive, and psychosocial support services to reduce their risk for transmitting or acquiring HIV infection. The guidelines recommend how counseling, testing, and referral can be provided to clients who could most benefit from these services across various settings and client populations.

### Subgroups Most Likely to Benefit:

Individuals in high HIV prevalence settings

## POTENTIAL HARMS

Not stated

# IMPLEMENTATION OF THE GUIDELINE

## DESCRIPTION OF IMPLEMENTATION STRATEGY

### Quality Assurance

Written quality assurance protocols should be developed, made available to all staff members providing counseling, referral, and testing services, and routinely implemented. All staff members should receive training and orientation regarding quality assurance. Quality assurance activities should address the following:

- Accessibility of services (e.g., hours of operation, location, availability of supplies and materials such as brochures, posters, test kits, safe injection materials, condoms, or lubricant).
- Compliance with written protocols for provision of service to an individual client (e.g., appropriate counseling protocols, timely return of HIV test results, referral for services responsive to client's priority needs).
- Services and materials appropriate to the client's culture, language, sex, sexual orientation, age, and developmental level.
- Staff performance/proficiency (e.g., competence, skills, credentials, and training).
- Supervision of staff members, including routine, timely feedback.
- Compliance with program guidelines and performance standards.
- Appropriateness of services to client needs, measured with client satisfaction tools (e.g., surveys or suggestion boxes).
- Record-keeping procedures, including confidentiality and security.
- Community resources (availability and collaborative arrangements).
- Collection, handling, and storage of specimens.
- Assurance of adequate funding and institutional support for counseling, referral, and testing services.

### Evaluation

Counseling, referral, and testing services should be continually evaluated to improve services to clients and provide accountability to stakeholders. Evaluation should be interactive, involving individual persons and organizations affected by the services. In public health settings, the community goals outlined in community health planning processes and other relevant local planning processes could be incorporated.

Providers should identify the key, relevant program goals and objectives that reflect services to the program, community, and client, and then determine what data are needed to evaluate those goals and objectives. Information obtained

from the evaluation should be used to plan and prioritize provision of counseling, referral, and testing services within a setting. For example, information from the HIV Counseling and Testing System (Centers for Disease Control and Prevention, National Center for HIV, STD, and TB Prevention, Division of HIV/AIDS Prevention) or locally available sources could be used during local community planning (e.g., HIV prevention community planning) to help develop or revise an HIV/AIDS prevention plan or describe who needs services. If resources for evaluation are limited, comprehensive evaluations (e.g., examining outcome or impact) might not be possible. However, even with limited resources, providers can conduct meaningful evaluations by focusing on relevant local outcomes.

### Data

Data collected should have a clear, anticipated use and should not be the focus of or interfere with provision of counseling, referral, and testing services. Data should be used to evaluate the extent to which the goals of counseling, referral, and testing and locally defined service outcomes (e.g., targeted return rates, knowledge of HIV infection status, proportion of successful referrals) are met. Although sound data are essential for evaluation of services, the primary purpose of each visit should be to provide the best possible service to the client. Data should be recorded outside the time reserved for counseling, referral, and testing discussions between the provider and the client. Clients could complete a questionnaire or intake information form on admission, providers could complete the forms immediately after meeting with a client, or a combination of the two approaches could be used.

Data collection methods should be compatible with the evaluation needs and priorities of the counseling, referral, and testing setting and locally defined service outcomes. Data should be collected with a standard collection instrument throughout the program. Simple data collection instruments (e.g., intake forms, medical record reviews) should be developed so data can be collected unobtrusively as part of the provision of services.

Publicly funded counseling, referral, and testing sites collect data on client demographic characteristics, risk behavior/exposure category, test acceptance, and type of site where service is provided. Most sites record the date of visit, anonymous or confidential test status, previous test result, current test result, and return for current test result for each client encounter. Additional data can be useful for evaluation of services, including date of previous test, type of current test (e.g., standard, rapid, oral fluid), risk-reduction plan summary, information relevant to any referrals made (e.g., provider and service description, information and materials provided, whether an appointment was made), whether the referral was received, type of service provided, dates when services were provided, and other relevant information (e.g., follow-up required, additional service needs).

### Confidentiality

Any data collected or recorded must be collected or recorded in a manner that ensures the confidentiality of the client. Clear procedures and protocol manuals must be developed and used.

### Ensuring High-Quality Evaluation

- The system used to collect the information must be monitored periodically to ensure data quality, which depends on the cooperative efforts of all persons providing counseling, referral, and testing services. Periodically, data collection systems should check records at each level of the data-collection process to ensure that information is recorded consistently and completely.
- Adequate training in the use of data collection instruments should be provided to all staff members to ensure that the evaluation process is not interfering with the provision of high-quality counseling, referral, and testing services.
- The information assembled during the evaluation process should be analyzed and reported in a timely manner to individual persons and organizations affected by the service.
- Information and feedback gained during the evaluation process should be used to improve the services offered by the site to the client.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Staying Healthy

### IOM DOMAIN

Effectiveness
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Revised guidelines for HIV counseling, testing, and referral. MMWR Recomm Rep 2001 Nov 9;50(RR-19):1-58. [151 references] PubMed

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2001 Nov 9

### GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

### SOURCE(S) OF FUNDING

United States Government

## GUIDELINE COMMITTEE

Not stated

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Centers for Disease Control and Prevention (CDC) Staff Members* Who Prepared This Report: Beatrice T. Divine, M.A.; Stacie M. Greby, D.V.M., M.P.H.; Kenneth V. Hunt; Mary L. Kamb, M.D., M.P.H.; Richard W. Steketee, M.D., M.P.H.; Lee Warner, M.P.H.; In consultation with Liisa M. Randall, M.A. from the National Alliance of State and Territorial AIDS Directors

*Division of HIV/AIDS Prevention - Surveillance and Epidemiology National Center for HIV, STD, and TB Prevention

Technical Expert Review Panel Members: Terje J. Anderson; David Atkins, M.D., M.P.H.; Catherine Baker-Cirac; Ronald Bayer, Ph.D.; Frank K. Beadle de Palomo, M.A.; Gail A. Bolan, M.D.; Carol A. Browning, M.S.; Scott Burris, J.D.; Amy S. DeGroff, M.P.H.; John M. Douglas, M.D.; Martin Fishbein, Ph.D.; Alice A. Gandelman, M.P.H.; Cynthia A. Getty; Lawrence O. Gostin, J.D., L.L.D.; Khurram S. Hassan, M.P.H.; Thomas L. Hearn, M.S., Ph.D.; Michael P. Johnson, M.D., M.P.H.; William J. Kassler, M.D., M.P.H.; Marlene LaLota, M.P.H.; Michael K. Lindsay, M.D., M.P.H.; Michael H. Merson, M.D.; Stephen F. Morin, M.A., Ph.D.; James Pearson, M.P.H., Ph.D.; Beny J. Primm, M.D.; Joel Rosenstock, M.D., M.P.H.; Peter Salovey, Ph.D.; Charles A. Schable, M.S.; Kathleen J. Sikkema, Ph.D.; Edith Springer, M.S.W.; Janis Spurlock-McLendon, M.S.W.; Lee Trevithick, M.A.; James Welch

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

## GUIDELINE STATUS

This is the current release of the guideline. These guidelines replace the Centers for Disease Control and Prevention (CDC) 1994 guidelines (HIV counseling, testing, and referral standards and guidelines. Atlanta [GA]: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, 1994).

An update is not in progress at this time.

## GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML format
- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

## AVAILABILITY OF COMPANION DOCUMENTS

None available

## PATIENT RESOURCES

None available

## NGC STATUS

This summary was completed by ECRI on April 12, 2002.

## COPYRIGHT STATEMENT



Date Modified: 11/15/2004